

In the Claims

Please cancel Claims 2, 3 and 16-32. Amend Claim 1 as follows. Amendments to the claim are indicated in the attached "Marked Up Version of Amendments" (pages i-ii).

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1. (Twice Amended) A method for quantitatively measuring the amount of an analyte of interest in a fluid sample, comprising:
- a) providing a membrane strip comprising an application point, a contact region, a sample capture zone and a control capture zone, wherein the contact region is between the application point and the sample capture zone and the sample capture zone is between the contact region and the control capture zone;
  - b) contacting the application point of the membrane strip with the fluid sample to be assayed for the analyte of interest;
  - c) maintaining the membrane strip under conditions which allow fluid to transport analyte of interest in the fluid sample by capillary action through the strip to and through the contact region, the contact region having a population of analyte-binding particles coated thereon and/or permeated therein, wherein the analyte-binding particles are coated with an analyte-binding agent;
  - d) further maintaining the membrane strip under conditions which allow analyte of interest, if present in the sample, to bind to analyte-binding particles, thereby generating contacted analyte-binding particles which may or may not have analyte of interest bound to analyte-binding agent on the analyte-binding particles; allow the fluid in the sample to mobilize and transport contacted analyte-binding particles by capillary action through the strip to and through the sample capture zone, the sample capture zone having a sample capture reagent immobilized thereon; and allow contacted analyte-binding particles to bind to the sample capture reagent;
  - e) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport contacted analyte-binding particles by capillary action through the strip to and through the control capture zone, the control capture zone having a control capture reagent immobilized thereon, wherein the control capture

reagent <sup>can</sup> react with analyte-binding particles but does not interact with the analyte of interest; and allow contacted analyte-binding particles to bind to the control capture reagent;


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- f) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport any contacted analyte-binding particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone;
  - g) determining the amount of contacted analyte-binding particles in the sample capture zone and the amount of contacted analyte-binding particles in the control capture zone;
  - h) determining a corrected analyte-binding particle amount, wherein the corrected analyte-binding particle amount is a ratio of the amount of analyte-binding particles in the sample capture zone, to the amount of analyte-binding particles in the control capture zone.
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Add the following claims:

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33. (New) A method for quantitatively measuring the amount of an analyte of interest in a fluid sample, comprising:
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- a) providing a membrane strip comprising an application point, a contact region, a sample capture zone and a control capture zone, wherein the contact region is between the application point and the sample capture zone and the sample capture zone is between the contact region and the control capture zone;
  - b) contacting the application point of the membrane strip with the fluid sample to be assayed for the analyte of interest;
  - c) maintaining the membrane strip under conditions which allow fluid to transport analyte of interest in the fluid sample by capillary action through the strip to and through the contact region, the contact region having a population of analyte-binding particles coated thereon and/or permeated therein, wherein the analyte-binding particles are coated with an analyte-binding agent;

- d) further maintaining the membrane strip under conditions which allow analyte of interest, if present in the sample, to bind to analyte-binding particles, thereby generating contacted analyte-binding particles which may or may not have analyte of interest bound to analyte-binding agent on the analyte-binding particles; allow the fluid in the sample to mobilize and transport contacted analyte-binding particles by capillary action through the strip to and through the sample capture zone, the sample capture zone having a sample capture reagent immobilized thereon; and allow contacted analyte-binding particles to bind to the sample capture reagent;
- e) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport contacted analyte-binding particles by capillary action through the strip to and through the control capture zone, the control capture zone having a control capture reagent immobilized thereon, wherein the control capture reagent can react with analyte-binding particles but does not interact with the analyte of interest; and allow contacted analyte-binding particles to bind to the control capture reagent;
- f) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport any contacted analyte-binding particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone;
- g) determining the amount of contacted analyte-binding particles in the sample capture zone and the amount of contacted analyte-binding particles in the control capture zone;
- h) determining a corrected analyte-binding particle amount, wherein the corrected analyte-binding particle amount is a ratio of the amount of analyte-binding particles in the sample capture zone, to the sum of the amount of analyte-binding particles in the control capture zone and the amount of analyte-binding particles in the sample capture zone.


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34. (New) The method of Claim 33, wherein the membrane strip is made of cellulose nitrate or glass fiber.
35. (New) The method of Claim 33, wherein the particles are latex beads.
36. (New) The method of Claim 33, wherein the particles are labeled.
37. (New) The method of Claim 36, wherein the label is selected from the group consisting of: colorimetric, fluorescent, phosphorescent, luminescent, chemiluminescent, and enzyme-linked molecule.
38. (New) The method of Claim 33, wherein the analyte and the analyte-binding agent are members of a binding pair, and one member of the binding pair is selected from the group consisting of: a protein, a hormone, an enzyme, a glycoprotein, a peptide, a small molecule, a polysaccharide, a lectin, an antibody, an antibody fragment, a nucleic acid, a drug, a drug conjugate, a toxin, a virus, a virus particle, a portion of a cell wall, a hapten, and a receptor.
39. (New) The method of Claim 33, wherein the analyte-binding agent is selected from the group consisting of: an antibody; an antibody fragment; a hapten; a drug conjugate; and a receptor.
40. (New) The method of Claim 39, wherein the analyte-binding agent is an antibody.
41. (New) The method of Claim 40, wherein the sample capture reagent is an antibody selected from the group consisting of: an antibody directed against the same epitope as the antibody on the analyte-binding particles, and an antibody directed against a different epitope as the antibody on the analyte-binding particles.

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